115 CMR 8.00: CERTIFICATION, LICENSING AND ENFORCEMENT

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8.01: Scope

- (1) Compliance with 115 CMR 8.00 and the requirements of 115 CMR in general is a prerequisite for licensure and certification. No provider may provide services and supports under contract or agreement with the Department unless those services and supports have been licensed and/or certified.
- (2) The Department shall determine, publish, and review periodically licensure and certification standards and procedures for the assessment of providers' compliance with Department regulations and the impact of services and supports on the quality of life of individuals served.
- (3) The Department shall license and/or certify:
 - (a) <u>Licensure</u>. All public and private providers offering residential supports, work/day supports, placement services, site-based respite, and any other services as deemed appropriate by the Department must be licensed, excluding those that are subject to licensure by another governmental agency with which there is written agreement between the Department and such agency for licensure exclusion.
 - (b) <u>Certification</u>. All public and private providers offering residential supports, work/day supports, placement services, site-based respite, individual supports, and any other services as deemed appropriate by the Department are subject to review of outcomes, in addition to those required for licensure that the Department determines are consistent with standards published in 115 CMR, excluding those that are subject to licensure or certification by another governmental agency with which there is written agreement between the Department and such agency for certification exclusion. The purpose of this review is to certify the overall quality of services and supports in specific quality of life domains set forth in 115 CMR 7.03.
 - (c) Any other person or organization providing only supports and services for persons with mental retardation and not subject to licensure or certification by another governmental agency, if the Department determines that the services are subject to the provisions of M.G.L. c. 19B.

8.02: Licensure, Certification, and Certification Renewal

- (1) The Department shall issue a license to providers of residential supports, work/day supports, placement services, or site-based respite supports to persons with mental retardation upon affirmative demonstration by the provider that the services and supports meet or exceed applicable licensure standards and regulations at 115 CMR.
- (2) Licenses issued under 115 CMR 8.01 through 8.09 shall be subject to revocation for cause and shall be non-transferable.
- (3) The Department shall certify the quality of providers of services and supports to determine whether the services and supports meet or exceed applicable certification standards and regulations at 115 CMR.
- (4) The Department may deem compliance with the overall quality of services and supports standards in the specific quality of life domains set forth at 115 CMR 7.03 upon receipt of current proof of accreditation by a national accreditation organization to be equivalent to certification upon evidence that the standards, survey process and survey outcomes of said accreditation organization are substantially similar to those of the Department and implement the goals and principles of the Department's Mission Statement. The Department shall periodically review the efficacy of the national accreditation organization findings to insure ongoing consistency with Department regulations, standards and mission statement. The Commissioner shall determine such national accreditation organizations acceptable for deeming under 115 CMR 8.02.

8.03: Application for Licensure and Certification or Renewal

- (1) Applicants for licensure and/or certification of new services or for renewal of licensure or certification shall file an application in writing with the Department in a manner and on a form prescribed by the Department.
- (2) Licensed providers that begin to provide new services or reconfigure existing services between surveys will be required to comply with pre-occupancy requirements set forth in 115 CMR 8.10, if applicable, but will not be subject to full survey until the next regularly scheduled renewal survey. Providers, however, are subject to a review of health, safety, and human rights protections at any time.
- (3) A provider not previously licensed that begins services shall, prior to the provision of service, apply for licensure in order to operate and shall be subject to an abbreviated survey of health, safety and human rights protections, within 60 days after service delivery begins.
- (4) The applicant must be the organization or person with principal legal responsibility for the administration and conduct of the provider.
- (5) The applicant shall submit, on forms or in a manner determined by the Department and subject to audit or inspection by the Department, such additional information as may be necessary for the Department to determine the qualifications of the applicant and its services for licensure or certification. Such information shall include, but is not limited to, all components of the applicant's services, staffing, financial status and service locations.
- (6) A provider will be deemed to be operating with a valid license as long as a current application is on record in the Office of Quality Management within the prescribed timeframe.

8.04: Licensure and Certification Survey

The Department shall survey each provider according to timelines in accordance with its licensure and certification status as determined in 115 CMR 8.05 and 8.06 and more frequently if deemed necessary to ensure compliance with 115 CMR. In accordance with 8.02(4), providers, other than those issued a one-year conditional license or that are recommended for non-licensure by the Department, may substitute a national accreditation process in *lieu* of the Department's certification survey. Surveys shall be conducted according to the following procedures:

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- (1) <u>Sample</u>. The Department will select for review a sample of individuals receiving services from or through the provider.
 - (a) The number or percentage of individuals reviewed shall be determined by the Department and shall exclude individuals in extenuating circumstances that would preclude their participation in the survey such as vacation, hospitalization, or other similar circumstance.
 - (b) The sample shall be representative of the provider's services and supports subject to licensure and certification.
 - (c) The Department may expand the selected sample during the conduct of a survey if, in the judgment of the survey team, serious issues arise in areas such as, but not limited to, medication, money management, health care, safety, human rights, behavior modification interventions, and further information is deemed necessary for thorough review.

(2) <u>Notification and Scheduling</u>.

- (a) The provider, regional and area offices, service coordinators, individuals selected as part of the sample for the survey and their guardians and family members, when appropriate, shall receive notification of the survey schedule.
- (b) Surveys shall ordinarily be made with prior notice and at reasonable times, giving due regard to the privacy of the individuals served and the interruption that the survey visit may cause. However, the Department shall have the right to review any service or support subject to licensure and/or certification under 115 CMR 8.00 at any time, without prior notice.
- (c) Refusal to permit a survey, with or without prior notice, shall be grounds for termination of contracts or agreements with the Department and/or the recommendation to terminate or deny licensure or certification. The provider shall make all relevant documents (as determined by the Department) available to the survey team upon request.
- (d) Survey scheduling shall be tailored to facilitate the participation of citizen volunteers.
- (3) <u>Survey Team</u>. Surveys shall be conducted under the supervision of the Department, which shall designate such Department employee(s) as it deems necessary to accomplish the purposes of the review. The size of the survey team shall vary depending on the size of the provider.
 - (a) In assembling the survey team the Department shall consider the language or method of communication of individuals included in the survey sample.
 - (b) The survey team leader may utilize Department staff, citizen volunteers and other professionals in the field of human services on the survey team, provided that the Department may exercise reasonable discretion in limiting the number of participants in any survey; and confidential information concerning individuals shall not be disclosed except in accordance with the confidentiality requirements of applicable state and federal law.
 - (c) Team members shall have no conflict of interest with the provider being surveyed and shall adhere to the conflict of interest statement developed by the Department. Prior to the conduct of the survey, providers may challenge the composition of the team on the basis of criteria outlined in the conflict of interest statement.
 - (d) All team members shall execute such documents as the Department determines are necessary to protect against unauthorized disclosure of confidential information in accordance with applicable state and federal law.
- (4) <u>Conduct of the Survey</u>. The Department shall conduct the following activities as part of the licensure and certification survey.
 - (a) <u>Observation</u>. Team members shall visit and observe the individual at the location where services or supports are provided. Team members will not routinely visit an individual at supported or competitive employment sites unless there is agreement between the individual, provider, and employer. Individuals selected as part of the sample who live in homes that they own, rent, or lease have a right to refuse a home visit. In addition, personal belongings, clothing, and storage spaces (closets, dressers, trunks, *etc.*) of any individual served shall not be subject to inspection by the Department without the consent of the individual.

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- (b) <u>Discussion</u>. Team members shall speak with individuals, staff, family members and guardians, and other significant people. The team member shall interview the service coordinator of each individual in the sample. The team member shall speak with other people such as human rights committee members or clinicians when additional information is needed to complete the survey assessment tool and assess compliance with 115 CMR. Individuals who refuse to be interviewed personally shall not receive a personal interview but shall remain in the sample and the quality of their services shall be evaluated.
- (c) <u>Review of Documentation</u>. Prior to and during the survey, team members shall review documents that provide information about the impact of services and supports on the quality of life of individuals served and about the organization and operation of the provider.
 - 1. Team members shall review documentation in an individual's record, including but not limited to the individual's ISP, progress notes, medication and health information, bank books, financial transaction sheets, and behavior modification plans, incident reports, and informed consents.
 - 2. Team members may review provider policies and procedures that include, but are not limited to, the following safeguards: emergencies (*e.g.* search and safety plans); restraint; money management; behavior interventions; human rights; medication administration; legal competency and guardianship; fire drill logs.
 - 3. On an as needed basis, other documentation may be reviewed, including but not limited to staff training, job descriptions, other policies and procedures, membership and minutes of the Human Rights Committee and peer review committee, education and teaching curriculum, mission statement, results of internal evaluations and strategic planning, staff evaluations, and other monitoring reports.
 - 4. The team members shall review the Department logs of complaints and Decision and Action Letters of investigations for the previous year.
 - 5. The team member may review the provider's system for conducting Criminal Offender Record Information (CORI) checks on all persons whose paid responsibilities may bring them into direct contact with individuals served.
- (5) <u>Feedback</u>. The team shall present the findings and results of the survey to the provider, and area and regional staff. The presentation shall include patterns and practices within each quality of life area reviewed, examples that serve to validate observations, and the provider's level of licensure and/or certification.
- (6) Immediate Jeopardy. Immediate jeopardy is defined as any circumstance in which the life, health, or safety of an individual(s) is severely threatened if the situation is not immediately corrected. A team member who observes a situation that places any individual in immediate jeopardy shall immediately notify the provider, the regional director and area director of the circumstances and the need to correct the situation within 48 hours unless otherwise indicated. The provider must take any and all action necessary to correct the situation. The team member will confirm that the situation has been corrected. If the situation is not corrected within the prescribed timeframe, that portion of the provider's services which are the subject of the review will not be licensed or certified until such time as corrective action has been taken.
- (7) <u>Action Required</u>. A team member who observes a situation that requires action in a timely manner shall immediately notify the provider, the regional and area director of the circumstances and the need to correct the situation within 30 days. The team member will confirm that the situation has been corrected.
- (8) In all cases where a condition reportable under 115 CMR 9.00 or M.G.L. c. 19C is observed, each team member is a mandated reporter and shall follow regulatory and statutory reporting procedures.

(9) Reports.

(a) An individual report outlining the results for quality of life domains on the survey shall be completed for each individual included in the survey sample and shall be sent to the provider and to the regional and area directors.

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- (b) A provider report shall be developed from a compilation of the individual findings and sent to the provider and to the regional and area directors. The provider report, modified to delete confidential personal information concerning individuals served, may be sent to any interested person upon request.
- (10) <u>Follow-up</u>. The Department shall follow-up with providers on all issues of immediate jeopardy, action required, and on all matters which have been identified as raising significant issues of rights and dignity or of personal well-being in the provider report.

8.05: Compliance and Levels of Licensure

- (1) A provider shall be in compliance with licensure requirements contained in 115 CMR 8.00, if:
 - (a) the provider has timely filed a sufficient application for licensure and certification or renewal and is participating in the licensure and certification survey process under 115 CMR 8.00; or
 - (b) the services and supports have been surveyed under 115 CMR 8.04 and found to meet the requirements for licensure; or
 - (c) in the event that the survey has identified conditions that require follow-up by the Department, the provider is participating in the follow-up process including having scheduled a follow-up survey; or
 - (d) the provider has obtained approval by the Department for a waiver under 115 CMR 8.09 and is in compliance with other requirements of licensure and all conditions or terms of the waiver issued in accordance with 115 CMR 8.09; or
 - (e) the provider has timely filed a written request for review of a de-licensure or denial of licensure decision with the Commissioner in accordance with 115 CMR 8.08(3);
 - (f) the provider has a pending appeal timely filed in accordance with 115 CMR 8.34.
- (2) Upon completion of the survey and receipt and review of all required documentation to the satisfaction of the Department, the Department may take the following actions:
 - (a) <u>Two-year License</u>. The Department shall issue a two-year license based upon complete achievement of the licensure standards developed under 115 CMR 8.01(2).
 - (b) <u>Conditional One-year License</u>. The Department shall issue a one-year conditional license based upon partial achievement of the licensure standards developed under 115 CMR 8.01(2). Until such time as the provider demonstrates complete achievement of licensure standards developed under 115 CMR 8.01(2), it shall be prohibited from accepting any new business.
 - (c) <u>Recommendation for Non-licensure</u>. The Department shall issue a recommendation for non-licensure to indicate that a provider has:
 - 1. received a conditional one-year license for two consecutive years; or
 - 2. a rating of "not achieved" in either of the quality of life areas for personal well-being or rights as set forth in the licensure standards developed under 115 CMR 8.01(2).
- (3) Upon notification by the Office of Quality Management that non-licensure has been recommended for a provider, the regional director may either accept the recommendation not to license the provider or develop a specific action plan in conjunction with the provider to improve its services to individuals.
- (4) When a determination of non-licensure has been made and an action plan has been developed with the regional director, the provider shall be subject to a follow-up visit by a Department survey team no later than 90 days after the issuance of the provider report. If the follow-up visit determines that significant progress has been made toward achievement of compliance, the Department shall issue a conditional one-year license. If the follow-up visit does not indicate evidence of substantial improvements, a decision of non-licensure shall be issued. Until such time as the provider demonstrates complete achievement of licensure standards developed under 115 CMR 8.01(2), it shall be prohibited from accepting any new business.

8.06: Certification

The certification process reviews outcomes for individuals in addition to those required for licensure, as set forth in 115 CMR 7.03, for the purpose of emphasizing continuous service enhancement. Upon completion of the survey and receipt and review of all required documentation to the satisfaction of the Department, the Department shall certify the quality of provider services and supports.

- (1) <u>Certification</u>. Certification shall be valid for the term of the license issued in accordance with 115 CMR 8.05(2).
- (2) <u>Certification with Distinction</u>. The achievement of all applicable licensure and certification standards may result in the designation of distinctive status. Providers that receive certification with distinction shall be exempt from review of certification standards for a period of one licensure term following the current license.

8.07: Administrative Reconsideration

- (1) Within ten working days after receipt of the provider report, the provider may file a written request for an administrative reconsideration with the regional Quality Management director in all cases except with respect to a decision of non-licensure. Decisions of non-licensure are subject to separate review and appeal through 115 CMR 8.34 and are not subject to administrative reconsideration.
- (2) The basis for a request for administrative reconsideration shall be:
 - (a) the facts or the conclusions in the provider report;
 - (b) the timelines for follow-up and correction of areas needing improvement.
- (3) Administrative reconsideration may not be requested on the basis of provider disagreement with:
 - (a) the content and/or values of the survey tool;
 - (b) the composition of the team;
 - (c) the methodology developed for scoring the survey.
- (4) Within 30 working days of the receipt of the request for reconsideration, the Department shall render a written decision that shall state its conclusions and rationale.
- (5) Within ten working days of receipt of the written decision, the provider may file a written request for a second level of administrative reconsideration.
- (6) The Department shall render a decision within 30 working days of receipt of the request. The decision rendered at the second level of administrative reconsideration is final and not subject to further review.
- (7) Administrative reconsideration shall be conducted by the Department by a person or organization designated by the Commissioner.

8.08: Review and Appeal

- (1) The Deputy Commissioner, the Assistant Commissioners for Quality Management and Operations, and the General Counsel will jointly review all recommendations for denial of licensure or license renewal prior to a final recommendation being presented to the Commissioner by the Office of Quality Management.
- (2) All decisions to deny a license or to de-license must be issued in writing by the Commissioner and must be accompanied by the provider report that delineates those specific areas in which the provider has been found to be in non-compliance with standards set by the Department.

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- (3) Within ten working days of receipt of a decision to deny a license or to de-license, the provider may request a Commissioner's review of the decision. The Commissioner retains final authority over all licensure decisions.
- (4) A decision to deny a license or to de-license shall result in the non-issuance or termination of the provider's license to operate the surveyed services and supports in accordance with 115 CMR 8.21 and is subject to appeal through 115 CMR 8.34.

8.09: Waiver

- (1) The requirements of 115 CMR shall be strictly enforced, and shall not be subject to waiver, except as specifically authorized by the Department in accordance with the provisions of 115 CMR 8.09 or within the context of the safety plan as specified in 115 CMR 7.06(4), 7.07(8), and 7.08(7)(c).
- (2) No waiver may be granted by the Department without a petition by the provider and a determination by the Department that:
 - (a) The health, safety, or welfare of individuals served and staff will not be adversely affected by granting the waiver; and
 - (b) the provider, in petitioning for the waiver, has stated an alternative standard which is found by the Department to result in a comparable quantity and quality of services and supports, and to which the applicant agrees to be held accountable to the same degree and manner as any provision of 115 CMR.
- (3) Waivers shall be granted for the duration of the licensure period or for a shorter duration, and may be renewable.

8.10: Approval for Occupancy

- (1) Approval for Occupancy is required for any home where 24-hour staffing is provided and where the home is owned, rented or leased by the provider; in all locations where work/day services are provided; and in locations where site-based respite services are provided.
- (2) Approval for occupancy for a new service shall precede licensure by the Department and is based on a site feasibility review, pre-placement visit, and approval by the Department, in accordance with 115 CMR 8.05. For such services and supports, the full survey required for licensure shall occur after occupancy and in accordance with 115 CMR 8.03 and 8.04.
- (3) The location inspection and issuance of an Approval to Occupy shall be in accordance with procedures and guidelines developed by the Department.

8.21: Issuance of Licenses

- (1) The Department shall issue a license to operate based upon the licensure status of the provider as determined in accordance with 115 CMR 8.05.
- (2) Determination of non-licensure status shall result in the denial or revocation of a license to operate.

8.30: Operation of Unlicensed Services and Supports

- (1) When the Department has reason to believe that a provider is operating a service or support which is subject to licensure by the Department without a valid and current license, and the provider has failed to apply for licensure within 30 days after notice by the Department, the Department may:
 - (a) Notify the District Attorney with jurisdiction over the provider that the provider is operating in violation of M.G.L. c. 19B, § 15; and
 - (b) Petition the Superior Court with jurisdiction over the provider to cease its operation or to take such other actions as may be necessary in the interest of the individuals served; and

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(c) Remove individuals for whom the Department is purchasing services and provide them with the most adequate and appropriate alternative arrangement available.

8.31: Visits by the Department

Any employee of the Department authorized by the Commissioner may visit and survey the location of any services which are subject to licensure and/or certification or regulation by the Department, in order to determine whether such services are being operated in compliance with law and with the regulations established by the Department.

8.32: Compliance Order

- (1) In addition to the procedures for determining licensure status set forth in 115 CMR 8.05, whenever the Department finds upon visit or through information that a provider is not in compliance with any applicable law or regulation, the Department may issue a compliance order for the correction of the deficiency or the suspension of the license, as deemed in the best interests of the individuals served.
- (2) Every such compliance order shall be in writing and shall include a statement of the deficiencies found, the period within which the deficiency must be corrected, and the provisions of law and regulations relied upon.
- (3) Within ten days of the issuance of a compliance order, the provider may file a written request with the Office of Quality Management for administrative reconsideration of the findings or any portion thereof, in accordance with 115 CMR 8.07. Compliance orders suspending or revoking a provider's license may be appealed pursuant to 115 CMR 8.34 or 8.35, as applicable. The filing of a request for administrative reconsideration shall not stay a provider's obligation to comply with the compliance order.
- (4) In the event that the provider fails to correct any deficiency within the period prescribed for correction, the Department shall enforce its compliance order under 115 CMR 8.33 or 115 CMR 8.35 or in accordance with M.G.L. c. 19B, § 15.

8.33: Suspension, Revocation, and Denial of License or Renewal

- (1) The Department may suspend, revoke or deny a license or renewal if it finds any of the following:
 - (a) The provider failed to comply with any applicable regulations or any compliance order;
 - (b) The provider received a de-licensure status upon completion of a survey;
 - (c) The provider furnished or made any misleading or false statement or report required under 115 CMR;
 - (d) The provider refused to submit or make available any reports required under 115 CMR;
 - (e) The provider refused to admit at any time for inspection any employee of the Department authorized by the Commissioner to conduct such inspections in accordance with 115 CMR 8.31;
 - (f) The provider or any of its staff was found after investigation pursuant to 115 CMR 9.00 or M.G.L. c. 19C to have committed gross neglect of an individual it serves or served;
 - (g) The provider or any of its staff knowingly or unknowingly permitted grave physical harm or sexual, physical, emotional or financial abuse of an individual to occur, by reason of failure to implement recommendations made by the Department after investigation of previous allegations of abuse, or by reason of reckless disregard for the safety or welfare of any individual.

8.34: Review and Appeal

Within 30 days of the receipt of a written request to the Commissioner by a provider denied licensure under 115 CMR 8.33, a hearing shall be held in accordance with the applicable requirements of M.G.L. c. 30A.

8.35: Suspension in Emergencies

- (1) The Department may temporarily suspend any license without a hearing if the failure of the provider to comply with any applicable regulation or standard appears to have resulted in an emergency situation that could endanger the life, safety, or health of individuals or staff within the service or support, or if it finds that such suspension is otherwise in the public interest.
- (2) Immediately upon such suspension, the Department shall notify the individuals served and their families and guardians, if any, and shall immediately provide or arrange for the most adequate and appropriate alternative arrangements available, or take such other action, including but not limited to using Department employees to provide the service or support, as the Department deems adequate to protect the individuals served.
- (3) Upon written request of the aggrieved provider to the Commissioner, a hearing shall be held promptly after the license is suspended, in accordance with the applicable requirements of M.G.L. c. 30A.

8.36: Notification of Legal Proceedings

Every provider shall report in writing to the Commissioner any legal proceeding within ten days of initiation of proceedings brought by or against the provider or any person employed by the provider, if such proceeding arises out of circumstances related to the care, treatment, habilitation, supervision, or living environment of persons being served by this provider.

8.37: Change of Name, Ownership, Location, or Services

- (1) The provider shall provide prior notification in writing to the Department of any change in its name or in its ownership.
- (2) The provider shall notify the Department in writing of any change in its executive director of the services or supports.
- (3) The provider shall notify the Department in writing of any changes in the physical location of the service or support, or of any other changes which place the provider out of compliance with any regulation under 115 CMR, within ten days of the change.
- (4) The failure of a provider to notify the Department of any change of name, ownership, location, or services and supports shall be grounds for suspension or termination of the license.

REGULATORY AUTHORITY

115 CMR 8.00: M.G.L. c. 19B, §§ 1, 14 and 15 and c. 123B, § 2.

NON-TEXT PAGE